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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,687	04/16/2004	Lucile Miquerol	37991-0013	8859

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EXAMINER	
NOBLE, MARCIA STEPHENS	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,687	MIQUEROL ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-15 are pending. Claims 8, 14 and 15 are amended by preliminary amendment filed 1/25/2005.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a transgenic mouse that has integrated a reporter gene in the locus of the Cx40gene, classified in class 800, subclass 18.

II. Claims 10, drawn to a method of performing electrophysiological studies comprising applying an action potential stimulus and taking images of fluorescent tissue, classified in class 800, subclass 3.

III. Claims 11, drawn to a method of testing a compound for its ability to induce cardiac arrhythmia comprising administering the compound to a mouse and analyzing digital images, classified in class 800, subclass 3.

IV. Claims 12, drawn to a method of testing a compound for its ability to induce treat or prevent cardiac arrest comprising administering the compound to a mouse, inducing ventricle fibrillation and analyzing digital images, classified in class 800, subclass 3.

V. Claims 13-15, drawn to a method of testing a compound for its ability to induce treat or prevent cardiovascular disease comprising administering

the compound to a mouse and analyzing digital images, classified in class 800, subclass 3.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the instant method of screening compounds can be used with any mouse that has a fluorescent marker associated with any gene of cardiac function because the steps of administering a drug, inducing an action potential or inducing a cardiac disease can be done in any mouse and is the same for any mouse. Similarly the steps of imaging a marker are the same no matter what the marker is detecting. Therefore, there is nothing unique about the mouse that requires that it is only mouse that can be utilized in the instant method. Therefore, the method of group II is distinct from the product of group I. Furthermore, the mouse of group I can be used in multiple, distinct methods as exemplified by groups II-V.

3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the instant method of screening compounds can be used with any mouse that has a fluorescent marker associated with any gene of cardiac function because the steps of administering a drug, inducing an action potential or inducing a cardiac disease can be done in any mouse and is the same for any mouse. Similarly the steps of imaging a marker are the same no matter what the marker is detecting. Therefore, there is nothing unique about the mouse that requires that it is only mouse that can be utilized in the instant method. Therefore, the method of group II is distinct from the product of group I. Furthermore, the mouse of group I can be used in multiple, distinct methods as exemplified by groups II-V.

4. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the instant method of screening compounds can be used with any mouse that has a fluorescent marker associated with any gene of cardiac function because the steps of administering a drug, inducing an action potential or inducing a cardiac disease can be done in any mouse and is the same for any mouse. Similarly the steps of imaging a marker are the

same no matter what the marker is detecting. Therefore, there is nothing unique about the mouse that requires that it is only mouse that can be utilized in the instant method. Therefore, the method of group II is distinct from the product of group I. Furthermore, the mouse of group I can be used in multiple, distinct methods as exemplified by groups II-V.

5. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the instant method of screening compounds can be used with any mouse that has a fluorescent marker associated with any gene of cardiac function because the steps of administering a drug, inducing an action potential or inducing a cardiac disease can be done in any mouse and is the same for any mouse. Similarly the steps of imaging a marker are the same no matter what the marker is detecting. Therefore, there is nothing unique about the mouse that requires that it is only mouse that can be utilized in the instant method. Therefore, the method of group II is distinct from the product of group I. Furthermore, the mouse of group I can be used in multiple, distinct methods as exemplified by groups II-V.

6. Inventions II and III are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are drawn to a method of performing an electrophysiological study and (group II) and a method of testing a compound for its ability to induce cardiac arrhythmias (Group III). The electrophysiological study requires different steps such as applying an action potential stimulus that are not required in the compound screening methods. Also the compound screening method also required different steps, such as administering a compound and testing its ability to induce arrhythmias that is not required by the electrophysiology method. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

7. Inventions II and IV are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are drawn to a method of performing an electrophysiological study and (group II) and a method of testing a compound for its ability to treat or prevent

cardiac arrest (Group IV). The electrophysiological study requires different steps such as applying an action potential stimulus that are not required in the compound screening methods. Also the compound screening method requires different steps, such as administering a compound, inducing ventricular fibrillation, and testing the ability of the compound to treat or prevent cardiac arrest that is not required by the electrophysiology method. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

8. Inventions II and V are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are drawn to a method of performing an electrophysiological study and (group II) and a method of testing a compound for its ability to treat or prevent cardiovascular disease (Group V). The electrophysiological study requires different steps such as applying an action potential stimulus that is not required in the compound screening methods. Also the compound screening method requires different steps, such as administering a compound and testing the ability of the compound to treat or prevent cardiovascular disease that is not required by the electrophysiology method. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

9. Inventions III and IV are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are drawn to method of testing a compound for its ability to induce cardiac arrhythmias (Group III) and a method of testing a compound for its ability to treat or prevent cardiac arrest (Group IV). The method for screening compounds that induce arrhythmias require steps to determine if the compound results in arrhythmia, which is not required by the method of screening a compound that treats cardiac arrest. Also the method of screening compounds that treat or prevent cardiac arrest require different steps, such as inducing fibrillation and testing for parameters of cardiac arrest, which are not present in the method of screening for arrhythmia-inducing drugs. Also one method encompasses a means of inducing a pathology, arrhythmia, where as the latter encompasses a means of reducing a pathology. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

10. Inventions III and V are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the

inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are drawn to method of testing a compound for its ability to induce cardiac arrhythmias (Group III) and a method of testing a compound for its ability to treat or prevent cardiovascular disease (Group V). The method for screening compounds that induce arrhythmias requires steps to determine if the compound results in arrhythmia, which is not required by the method of screening a compound that treats cardiovascular disease. Also one method encompasses a means of inducing a pathology, arrhythmia, where as the latter encompasses a means of reducing a pathology. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

11. Inventions IV and V are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are drawn to a method of testing a compound for its ability to treat or prevent cardiac arrest (Group IV) and a method of testing a compound for its ability to treat or prevent cardiovascular disease (Group V). The method of screening compounds that treat or prevent cardiac arrest requires different steps, such as inducing fibrillation and testing for parameters of cardiac arrest, which is not required by the

method of screening a compound that treats cardiovascular disease. Also the method of screening compounds that treat or prevent cardiovascular disease require different steps, such as testing for parameters of cardiovascular disease, which are not present in the method of screening for cardiac arrest. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached at (571)-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble